510(k) SUMMARY

The 510(k) Summary is submitted as required by Section 807.92(a)

Submitter Name:	Volcano Corporation
Contact Person:	Lorry W. Huffman, RAC, MT(ASCP), CLS(NCA) Sr. Director Regulatory Affairs
Address:	2870 Kilgore Road Rancho Cordova, CA 95670
Phone Number:	916-281-4503
Fax Number:	916-638-2647
Date Prepared:	June 4, 2007
Device Trade Name:	**Volcano s5/s5i Series Intravascular Imaging and Pressure Systems**
Device Common Name:	Ultrasonic imaging system
Classification Name, Number, Product Code:	892.1560 Ultrasonic pulsed echo imaging system, II, IYO 870.1110 Blood Pressure Computer, II, DSK 870.2900 Patient Transducer and Electrical Cable, II, DSA

Predicate Device Table

Predicate System Name	Predicate System 510(k) Clearance	Current Catalog Numbers	Predicate Catheters/Wires 510(k) Clearance	Current Catalog Numbers
Volcano s5i Family of Imaging Systems	K061215	s5/806300-001 s5/806300-003	K051337 K000820 K944004 K902329	85900 Eagle Eye Gold 85700 Avanar FX 2.9F 86700 PV 0.018 88900 PV8.2
Volcano s5 Imaging System	K051920	s5/804200-001	K051337 K000820 K944004 K902329	85900 Eagle Eye Gold 85700 Avanar FX 2.9F 86700 PV 0.018 88900 PV8.2
ComboMap® Pressure and Flow System	K041134	6800	K021219 K070487 K042996	SmartWire II/BrightWire II 6600, 6600J, 6603, 6603J, 6613, 6613J (7600, 7600J, 7603, 7603J) FloWire 1400, 1400J, 1401, 1401J, 1403, 1403J, 1404, 1404J, 1413, 1413J ComboWire II 9603, 9610
VH IVUS® System	K051337	804906-001 804907-001 804908-001 804911-001	K051337	85900 Eagle Eye Gold
In-Vision Gold with SpinVision	K052348	804906-001 804907-001 804908-001 804911-001	K050995 K051337 K000820 K944004 K902329	89000 Revolution 85900 Eagle Eye Gold 85700 Avanar FX 2.9F 86700 PV 0.018 88900 PV8.2

Other prior predicates:
WaveMap cleared under K965140; SmartMap cleared under K021219; ColorFlo Option for the Oracle InVision Intravascular Ultrasound Imaging System cleared under K963290 on August 6, 1997; the Resolve Option for the Oracle InVision Intravascular Ultrasound Imaging System cleared under K965223 on June 29, 1998, the InVision Imaging System cleared under K031148 on May 28, 2003.

NOTE: Volcano Therapeutics, Inc. (now Volcano Corporation) purchased the assets of JOMED Inc. on July 21, 2003. JOMED Inc. purchased Endosonics Corporation.

Device Description:

General Operation Overview

When operating in IVUS mode, the system console gathers and displays high-resolution intraluminal images that can be analyzed both qualitatively and quantitatively. In addition to supplying diagnostic information, the Volcano s5/s5i system is an adjunct to interventional therapies, such as balloon angioplasty. With ChromoFlo® (not available with Revolution catheter), a two-dimensional color map of relative blood velocities is overlaid on the grayscale image, providing additional information for vessel analysis. The In-Line Digital feature displays a two-dimensional, longitudinal view of the vessel. The angle of the longitudinal cut can be varied around the full 360 degrees.

When operating in pressure mode, the system acquires intraluminal data from the pressure guidewire (SmartWire II/ComboWire) while simultaneously taking aortic pressure data from the established ECG/EKG catheterization lab equipment. In conjunction with the procedure, the system measures pressure and calculates pressure differences between the aoritic pressure and the SmartWire/ComboWire pressure transducer typically located distal to the vascular lesion and calculates the fractional flow reserve (FFR).

Volcano s5/s5i Series Intravascular System (Subject Device)

s5 tower or portable configuration Model 807300-xxx
s5i integrated configuration Model 807400-xxx
s5i integrated configuration with 3rd party connectivity Model Multiple, TBD

Accessories and Option kits

s5-rev Option Kit part number 806071-008
s5i-rev Option Kit part number 806071-009
s5-ffr Option Kit part number 807342-001
s5i-ffr Option Kit part number 807343-001
S5i PIMr rail Hanger Option Kit part number 807334-001
s5 PC Chassis Upgrade Kit part number 807301-004
Multiple peripheral components part number(s) Multiple, refer to Marketing brochure in Attachment 4 for a current listing

Catheters
- 85900 Eagle Eye Gold
- 85700 Avanar FX 2.9F
- 86700 PV 0.018
- 88900 PV8.2
- 89000 Revolution 45 MHz Rotational

Wires

SmartWire II	6600	6600J
	6603	6603J
	6613	6613J
BrightWire II	7600	7600J
	7606	7603J
ComboWire II	9603	9610

(operates the pressure transducer only)

Intended Use:
The Volcano s5/s5i Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo® is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

VH IVUS is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano VH IVUS System is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular features that the user may wish to examine more closely during routine diagnostic ultrasound imaging examinations.

The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature. As an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures. The pullback feature of the PIMr withdraws the imaging core within the protective sheath for a maximum of 15 cm.

Performance Data:
A risk analysis was conducted according to 803475-001 *Risk Management* which was written to comply with ISO 14971 and IEC 60601-1-4 as specific risk management standards. Also taken into consideration in this procedure are 21 CFR 820.30 and the Medical Device Directive of the European Union (93/46/EEC). Applicable testing was performed as required by the Quality System to evaluate the modifications to the Volcano s5/s5i Intravascular Imaging and Pressure System. The test results were found to be acceptable as required by the respective test plans and protocols.

Conclusion:
The discussion and data presented in this 510(k) and conformance with Design Controls and the Quality System Regulations establishes the Volcano s5/s5i Series Intravascular Imaging and Pressure System to be substantially equivalent for its intended use to the predicate devices listed in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2008

Volcano Corporation
c/o Lorry Huffman, RAC
Sr. Director, Regulatory Affairs
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K071554
Trade Name: Volcano s5/s5i Intravascular Imaging and Pressure System
Regulation Number: 21 CFR 870.1200
Regulation Name: Intravascular Ultrasound Catheter
Regulatory Class: Class II (two)
Product Code: OBJ, IYO
Dated: December 3, 2007
Received: December 5, 2007

Dear Ms. Huffman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K071554

Device Name: Volcano s5/s5i Series Intravascular Imaging and Pressure System

Indications for Use:

The Volcano s5/s5i Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071554

(Posted November 13, 2003)